**LARSEN & TOUBRO LIMITED**

ELECTRICAL BUSINESS GROUP - ELECTRONIC PRODUCTS

Mysore Works. KIADB Industrial Area. Hebbal - Hootagalli, Mysore - 571 186 • Tel : (91) - 821- 402561 • Fax : (91) - 821 - 402468

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Ref

7th October 2003
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## 510(K) SUMMARY

(Per section 807.92 ©)

| CONTACT DATA | | | |
|---|---|---|---|
| **Submitter's Name** | | Larsen & Toubro Limited | |
| **Address** | | KIADB Industrial Area, Hebbal Hootagalli, Mysore – 570018, Karnataka, INDIA | |
| **Telephone** | 91-821-402561 | **Fax** | 91-821-402468 |
| **Contact Person** | A.B.Deshpande | **Title** | Head – Quality Assurance & customer support |
| **E-Mail address** | | DeshpandeAB@myw.ltindia.com | |
| **Date the summary was prepared** | | October 7,2003 | |

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| DEVICE | |
|---|---|
| **Trade name** | STAR (LUNAR SERIES) |
| **Common name** | Patient Monitoring System |
| **Classification name** | Vital Signs Monitor |

| PREDICATE DEVICE IDENTIFICATION | | | |
|---|---|---|---|
| **CFR21 Section** | 870.2300 | **Product code (optional)** | MWI |
| **Classification panel** | | Cardiovascular | |
| **Device Class** | | Class II | |
| **Legally marketed Comparison Device / K#** | | • Eagle 3000 patient Monitoring System (Marquette Electronic) / K952474<br>• Vital signs monitor Model 8100 (CSI) / K001020 | |

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## DEVICE DESCRIPTION

This STAR unit is a multiparameter Patient monitor System (TFT color monitor) with ECG(3/5 lead), Respiration, Temperature, NIBP, Pulse oximetry and Invasive BP.
STAR is a four channel monitor with waveform display capability for ECG (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration and Invasive Blood pressure (IBP1 & IBP2). It also displays the digital values of HR/PR, $SpO_2$, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings. It has graded and color coded alarms. It has 24 hours tabular and graphical trends for all parameters except NIBP. For NIBP the last 240 readings tabular trend can be seen. Display of last 16 alarm conditions is possible in alarm recall mode. Print out of tabular trend and ECG waveform can be obtained through an optional inkjet printer or paper chart recorder.

## INTENDED USE OF THE DEVICE

The STAR (LUNAR SERIES) multiparameter Patient Monitoring system is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration and Invasive Blood pressure (IBP1 & IBP2). It can also display the digital values of HR/PR, $SpO_2$, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings.
The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device, which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

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Ref .

## TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

**Device :** Larsen & Toubro limited make STAR(LUNAR series) Patient Monitoring System.

**Predicate device :**

Eagle 3000 patient Monitoring System (Marquette Electronic), K# K952474

Vital signs monitor Model 8100 (CSI), K# K001020

The parameters available with these predicate devices are available with the Larsen & Toubro Limited make STAR (LUNAR series) patient monitoring system (ECG-3/5 lead, Respiration, Temperature – 2 channels, NIBP, Pulse oximetry and Invasive BP- 2 channels). The no. of channels, range and accuracy of the parameters & method of sensing are similar to the predicate devices. In STAR monitor audible & visual alarms are provided similar to those in the Predicate devices.
STAR has got TFT color display like CSI Model 8100. Weight is also comparable with that of Marquette Eagle 3000. Battery (2 sealed lead acid) is provided in STAR monitor like that of the predicate device CSI Model 8100.

Comparison of all the parameters of STAR to that of the predicate devices is given in the "Substantial Equivalence Equipment comparison" document.

**Compliance to standards:**
Testing were conducted, which demonstrate safety and effectiveness to the following international standards.
IEC 60601-1 Medical Electrical safety
IEC 60601-1-2 EMC compliance
IEC 60601-2-27 ECG safety

**Conclusion:**
Based on the Technological characteristics of STAR (LUNAR series) and its comparison with those of a predicate device CSI Model 8100 and Marquettee Eagle 3000 monitors, Larsen & Toubro Limited believes that their device is substantially equivalent to these Monitors and doesn't pose any additional risk on safety & effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 0 2003

Larsen & Toubro Ltd.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K032867
Trade Name: STAR (LUNAR Series)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 29, 2003
Received: October 30, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032867



# Indication for Use statement

510(k) Number (if known) _____

Device name: STAR (LUNAR series)

Indication for use:

The STAR (LUNAR SERIES) multiparameter Patient Monitoring system is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameters include ECG (Lead I / II / III / V / AVL / AVF / AVR), Plethysmograph, Respiration and Invasive Blood pressure (IBP1 & IBP2). It can also display the digital values of HR/PR, $SpO_2$, RR, Non-Invasive & Invasive Blood Pressure (Systolic, Diastolic and Mean) and Temperature readings.
The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device, which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER RPAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Melissa Mapa for BDE
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032867

Prescription Use ____ OR Over-the –counter-use _____
(Per 21 CFR 801.109)